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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,357	09/18/2006	**Stefan Verseck**	009848-0356700	8910

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EXAMINER	
STRZELECKA, TERESA E	
ART UNIT	**PAPER NUMBER**
1637	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,357	VERSECK ET AL.	
	Examiner	Art Unit	
	TERESA E. STRZELECKA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *1-5,7,8,10 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/18/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III (claims 6 and 9) in the reply filed on October 3, 2008 is acknowledged. The traversal is on the ground(s) that the cited reference, Falon et al. (WO 97/12964) is not a prior art against the claims, since it was not published before the priority date of the instant application, which is March 20, 2004. This is not found persuasive because the Falon et al. publication was published on April 10, 1997. Since 1997 occurred before 2004, the Falon et al. reference predates the priority date of the instant application by nearly seven years. Therefore, Falon et al. constitutes prior art with respect to instant claims.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-5, 7, 8, 10 and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 3, 2008.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. Claims 6 and 9 will be examined.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on September 18, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 6 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number'' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of amino acid sequences which are different from those disclosed in the specification. The genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named SEQ ID NOs 39, 45, 49, 57 and 59 for the α-subunits of a nitrile

hydratase and SEQ ID NOs 63 and 71 for the β-subunits of a nitrile hydratase. Thus, applicant has express possession of only seven particular sequences, in a genus which comprises hundreds of millions of different possibilities. Here, no common element or attributes of the sequences are disclosed, not even the presence of certain domains. No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations is provided. Further, these claims encompass alternately spliced versions of the proteins, allelic variants including insertions and mutations, inactive precursor proteins which have a removable amino terminal end, and only specific amino acid sequences have been provided. No written description of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

Specifically, the claims are drawn to a "protein sequence which is required for constructing the activity of a nitrile hydratase and which has less than 100% homology, at the amino acid level, with such known protein sequences". First, search for "nitrile hydratase" in the protein database of PubMed lists 4281 sequences. Applicants did not define what constitutes a sequence required for constructing the activity of a nitrile hydratase, therefore in principle, any of the above 4281 sequences, plus their fragments, mutants, etc., anticipates this term, therefore, there are millions such sequences. Further, as described by Applicants on page 2, lines 18-34, the nitrile hydratases can form multimeric proteins composed of different numbers of α-subunits and β-subunits. Finally, as described by Applicants on page 8, lines 11-22, additional proteins are usually required for the nitrile hydratase activity, and thus their sequences fall within the scope of instant claims. In conclusion, the genus claimed in claim 9 is not represented by the disclosed SEQ ID NOs.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

> "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the "protein sequence which is required for constructing the activity of a nitrile hydratase and which has less than 100% homology, at the amino acid level, with such known protein sequences" lacks any specific structure, and is precisely the situation of naming a type of material which is generally known to likely exist, but, except for the seven specific sequences, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim to a "protein sequence which is required for constructing the activity of a nitrile hydratase and which has less than 100% homology, at the amino acid level, with such known protein sequences", for example.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound solely but its functional utility, as a nitrile hydratase, without any definition of the particular function claimed.

In the instant application, certain specific SEQ ID NOs are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any polypeptides other than those expressly disclosed. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 6 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 9 are rejected over the recitation of "protein sequence which is required for constructing the activity of a nitrile hydratase and which has less than 100% homology, at the amino acid level, with such known protein sequences". It is not clear what it means that the protein sequence has less than 100% homology "with such known protein sequences". First, the claim does not require that the "protein sequences" be sequences of nitrile hydratases, therefore, it is not clear what sequences they need to be compared to. Then there is an issue of "known protein sequences". When were those sequences known? Before the filing date of the instant application, or at any time afterwards as well? For these reasons, claims 6 and 9 do not have clear metes and bounds.

Claim Interpretation

10. The phrase " a protein sequence which is required for constructing the activity of a nitrile hydratase and which has less than 100% homology, at the amino acid level, with such known

protein sequences" is interpreted as any sequence which has less than 100% sequence homology with any known nitrile hydratase.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Fallon et al. (WO 97/12964; cited in the IDS).

Regarding claims 6 and 9, Falon et al. teach α- and β-subunits of a nitrile hydratase with amino acid sequences of SEQ ID NO: 1 and 2, respectively (page 5, lines 32-38; page 6, lines 1-13; page 16, lines 9-14; page 21, lines 9-14). As evidenced by the BLAST search results of SEQ ID NO: 3 of Fallon et al. (nucleic acid encoding SEQ ID NO: 1), SEQ ID NO: 3 of Fallon et al. is identical to the sequence with GenBank Accession No. U89363.1, published January 28, 2000. The α- and β-subunits encoded by the nucleic acid sequences of Fallon et al. were compared to α- and β-subunits of a nitrile hydratase with GenBank accession No. X64360, originally published on February 26, 1993. As can be seen from the sequence alignments, the α-subunit of Falon et al. has 63% amino acid identity with the α-subunit of GenBank accession No. X64360, and the β-subunit of Falon et al. has 37% amino acid identity with the β-subunit of GenBank accession No. X64360, anticipating the limitation of less than 100% amino acid sequence homology to known proteins.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 6 and 9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,288,402. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the '402 patent is a specie of the instant claims 6 and 9.

Claim 6 of the instant application is drawn to a protein sequence which is required for constructing the activity of a nitrile hydratase and which has less than 100% homology, at the amino acid level, with such known protein sequences, with the nucleic acid sequences encoding it being generated from part sequences which give a positive hybridization signal, under stringent conditions, with the primers exhibiting the nucleic acid sequences of claim 1. Claim 9 of the instant application is drawn to a nitrile hydratase which exhibits protein sequences for α-subunits and β-subunits as claimed in claim 6

Specifically, claim 1 of the '402 patent is drawn to nitrile hydratase subunits with SEQ ID NO: 2 and 3, therefore, it anticipates the genus claimed in the instant claims 6 and 9.

15. Claims 6 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9 and 15 of copending Application No.

12/296,057. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 2, 9 and 15 of the Application No. 12/296,057 are species of the instant claims 6 and 9.

Claim 6 of the instant application is drawn to a protein sequence which is required for constructing the activity of a nitrile hydratase and which has less than 100% homology, at the amino acid level, with such known protein sequences, with the nucleic acid sequences encoding it being generated from part sequences which give a positive hybridization signal, under stringent conditions, with the primers exhibiting the nucleic acid sequences of claim 1. Claim 9 of the instant application is drawn to a nitrile hydratase which exhibits protein sequences for α-subunits and β-subunits as claimed in claim 6

Specifically, claims 1, 2, 9 and 15 of the Application No. 12/296,057 are drawn to nitrile hydratase subunits with SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18 and 20, therefore, they anticipate the genus claimed in the instant claims 6 and 9.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E. STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
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/Teresa E Strzelecka/
Primary Examiner, Art Unit 1637
November 30, 2008